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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,259	03/18/2004	Ralph B. Lilly	Anon-001:C	5397
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EXAMINER				
NAJARIAN, LENA				
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3686				
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07/30/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/803,259

**Applicant(s)**

LILLY ET AL.

**Examiner**

LENA NAJARIAN

**Art Unit**

3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-10 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the Request for Continued Examination (RCE) filed 6/3/09. Claims 1, 2, and 22-24 have been amended. Claims 5 and 11-21 are cancelled. Claims 1-4, 6-10, and 22-24 are pending.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/09 has been entered.

### ***Specification***

3. The objection under 35 U.S.C. 132(a) is hereby withdrawn due to the amendment filed 6/3/09.

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1 and 22-24 under 35 U.S.C. 112, first paragraph, is hereby withdrawn due to the amendment filed 6/3/09.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4, 6-10, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "complete prescription history" in claims 1 and 22 is a relative term which renders the claim indefinite. The term "*complete prescription history*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, it is unclear what the time frame or extent of the history is. For example, is it a complete prescription history of that day, month, year, lifetime, etc?

8. Claim 1 recites the limitation "said transferred pharmaceutical *computer data*" in line 19. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 2, 3, and 6 recite the limitation "said selected *prescriptive medication purchaser*" in lines 3 & 6 of claim 2, lines 4 & 7-8 of claim 3, and lines 3 & 5 of claim 6. There is insufficient antecedent basis for this limitation in the claims.

10. Claim 2, 3, 6, and 7 recite the limitation "said pharmaceutical *computer* data" in line 5 of claim 2, line 6 of claim 3, line 4 of claim 6, and line 2 of claim 7. There is insufficient antecedent basis for this limitation in the claims.
11. Claim 2, 3, 4, and 6 recite the limitation "said *prescriptive* history" in lines 5-6 of claim 2, line 7 of claim 3, line 3 of claim 4, and lines 4-5 of claim 6. There is insufficient antecedent basis for this limitation in the claims.
12. Claim 7 recites the limitation "said *prescriptive* medication purchases" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.
13. Claim 8 recites the limitation "said stored pharmaceutical *computer* data" in line 2. There is insufficient antecedent basis for this limitation in the claim.
14. Claim 22 recites the limitation "said complete *prescription* history" in line 15. There is insufficient antecedent basis for this limitation in the claim.
15. Claims 23 and 24 recite the limitation "the prescription history" in line 2 of claim 23 and line 2 of claim 24. There is insufficient antecedent basis for this limitation in the claims.
16. Claims 9 and 10 incorporate the deficiencies of claim 1 and 7, through dependency, and are also rejected.

***Claim Rejections - 35 USC § 101***

17. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

18. Claims 1-4, 6-10, and 22-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In order to qualify as a statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. The recited steps of independent claim 1 of merely providing respective computer *connections*, obtaining and storing data, transferring data, and generating patterns are not tied to another statutory class (such as a particular apparatus) and do not transform underlying subject matter (such as an article or materials) to a different state or thing. Similar analysis applies for independent claim 22. Therefore, claims 1-4, 6-10, and 22-24 are deemed to be directed to non-statutory subject matter.

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 1-4, 6-10 and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Denny (US 6,687,676 B1).

(A) Referring to claim 1, Cunningham discloses a method for tracking prescription medication, to address and control prescription drug abuse, said method comprising (abstract and col. 3, lines 54-56 of Cunningham):

providing respective computer connections to a plurality of entities, said plurality of entities comprising a plurality of affiliated pharmacies such that affiliated pharmacies maintain their own database of information (Fig. 1, col. 3, lines 4-10, and col. 4, lines 37-62 of Cunningham);

obtaining and storing pharmaceutical data related to prescription medication purchases by a plurality of purchasers from said plurality of affiliated pharmacies (col. 2, line 64 – col. 3, line 10 & col. 3, lines 40-67 of Cunningham; the Examiner interprets the "patients" to be a form of "purchasers"); and

selectively transferring said pharmaceutical data through said computer connections to at least one of said plurality of entities for obtaining a prescription history

of a selected purchaser of prescription medication based on said transferred pharmaceutical computer data (col. 3, lines 4-10 and col. 3, lines 54-67 of Cunningham).

Cunningham does not expressly disclose unaffiliated pharmacies and that a complete prescription history comprises all prescription medications purchased in the aggregate by said selected prescription medication purchaser from all of said plurality of affiliated *and* unaffiliated pharmacies and generating from said complete prescription history of said selected purchaser one or more patterns defined by the pharmaceutical data associated with the selected purchaser which patterns empower the identification of prescriptive drug abuse and the control thereof.

Denny discloses unaffiliated pharmacies and that a complete prescription history comprises all prescription medications purchased in the aggregate by said selected prescription medication purchaser from all of said plurality of affiliated and unaffiliated pharmacies and generating from said complete prescription history of said selected purchaser one or more patterns defined by the pharmaceutical data associated with the selected purchaser which patterns empower the identification of prescriptive drug abuse and the control thereof (Fig. 7, col. 3, lines 20-37, col. 4, lines 30-46, col. 6, lines 37-51, and col. 11, line 58 - col. 12, line 20 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The



motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

(B) Referring to claim 2, Cunningham discloses providing that said at least one of said plurality of entities comprises a physician's office and said selected prescriptive medication purchaser is a patient of said physician (col. 2, lines 40-44 and col. 6, lines 44-61 of Cunningham); and

said prescriber utilizing said pharmaceutical computer data (Fig. 1 of Cunningham).

Cunningham does not expressly disclose that the physician's office verifies said prescriptive history of said selected prescriptive medication purchaser.

Denny discloses the physician verifying said prescriptive history of said selected prescriptive medication purchaser (see abstract and col. 6, lines 37-51 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

(C) Referring to claim 3, Cunningham discloses providing that said at least one of said plurality of entities comprises a pharmacy with a pharmacist (col. 11, lines 38-40 of Cunningham);

said selected prescriptive medication purchaser requesting that said pharmacist fill a new prescriptive medication (col. 3, lines 54-57 of Cunningham); and

said pharmacist utilizing said pharmaceutical computer data to compare said new prescriptive medication with respect to said prescriptive history of said selected prescriptive medication purchaser (col. 3, lines 54-67 of Cunningham).

(D) Referring to claim 4, Cunningham discloses said pharmacist accepting or declining to fill said new prescriptive medication based on said prescriptive history (col. 3, lines 54-67 of Cunningham).

(E) Referring to claim 6, Cunningham does not expressly disclose providing that at least one of said plurality of entities comprises a hospital and said selected prescriptive medication purchaser is a patient of said hospital; and said hospital utilizing said pharmaceutical computer data to determine said prescriptive history of said selected prescriptive medication purchaser.

Denny discloses providing that at least one of said plurality of entities comprises a hospital and said selected prescriptive medication purchaser is a patient of said hospital (col. 3, lines 20-37 and col. 4, lines 30-46 of Denny); and said hospital utilizing said pharmaceutical computer data to determine said prescriptive history of said selected prescriptive medication purchaser (col. 6, lines 27-51 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

(F) Referring to claim 7, Cunningham discloses providing that said pharmaceutical computer data for each of said prescriptive medication purchases comprises a name of a respective prescriptive medication purchaser, a drug prescribed, said respective prescriptive medication purchaser, a quantity of said drug, a dosage of said drug, a pharmacist name, and a doctor name (col. 5, lines 16-60 and col. 6, lines 6-25 of Cunningham).

Cunningham does not disclose an address of said respective prescriptive medication purchaser.

Denny discloses an address of said respective prescriptive medication purchaser (col. 8, lines 41-53 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Denny within Cunningham. The motivation for doing so would have been to have complete patient information (col. 8, lines 41-53 of Denny).

(G) Referring to claim 8, Cunningham does not disclose searching said stored pharmaceutical computer data based on one or more of said name of a respective prescriptive medication purchaser, said address of said respective prescriptive medication purchaser, said drug prescribed, said respective prescriptive medication purchaser, said quantity of said drug, said dosage of said drug, said pharmacist name, and said doctor name.

Denny discloses searching said stored pharmaceutical computer data based on said drug prescribed (col. 11, lines 21-43 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Denny within Cunningham. The motivation for doing so would have been to determine whether the prescription has been filled (col. 11, lines 13-20 of Denny).

Insofar as the claim recites "one or more of," it is immaterial whether or not the other elements are also disclosed.

(H) Referring to claim 9, Cunningham discloses storing pharmaceutical data related to whether a request for filling a prescriptive medication is filled or declined (col. 3, lines 54-67 of Cunningham).

(I) Referring to claim 10, Cunningham discloses providing that at least one of said plurality of entities comprises a government agency (col. 2, lines 54-59 of Cunningham).

(J) Referring to claim 22, Cunningham discloses a method for tracking prescriptive medications, to address and control prescription drug abuse, said method comprising (abstract and col. 3, lines 54-56 of Cunningham);

providing respective computer connections to a plurality of entities, said plurality of entities being a group consisting essentially of a plurality of hospitals, a plurality of doctors, at least one government agency, or combinations thereof (Fig. 1, col. 4, lines 37-62, and abstract of Cunningham);

obtaining and storing pharmaceutical computer data relating to prescriptive medication purchases by a plurality of prescriptive medication purchasers from a plurality of pharmacies (col. 2, line 64 – col. 3, line 10 and col. 3, lines 40-67 of Cunningham; the Examiner interprets “patients” to be a form of “prescriptive medication purchasers”);

selectively transferring said pharmaceutical computer data through said computer connections to at least one of said plurality of entities for obtaining a prescriptive history of a selected prescriptive medication purchaser based on said transferred pharmaceutical computer data (col. 3, lines 4-10 and col. 3, lines 54-67 of Cunningham).

Cunningham does not expressly disclose a complete prescriptive history that comprises all prescriptive medications purchased in the aggregate by said selected prescriptive medication purchaser from all of said plurality of pharmacies and generating from said complete prescription history of said selected purchaser one or more patterns which flag prescriptive drug abuse.

Denny discloses a complete prescriptive history that comprises all prescriptive medications purchased in the aggregate by said selected prescriptive medication purchaser from all of said plurality of pharmacies and generating from said complete prescription history of said selected purchaser one or more patterns which flag prescriptive drug abuse (Fig. 7, col. 3, lines 20-37, col. 4, lines 30-46, col. 6, lines 37-51, and col. 11, line 58 - col. 12, line 20 of Denny).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud (col. 1, lines 23-27 of Denny).

21. Claims 23 and 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Denny (US 6,687,676 B1), and further in view of Edelson et al. (5,737,539).

(A) Referring to claims 23 and 24, Cunningham and Denny do not expressly disclose wherein the one or more patterns from the prescription history indicate prescription duplication, multi-source prescription abuse, or combinations thereof.

Edelson discloses wherein the one or more patterns from the prescription history indicate prescription duplication, multi-source prescription abuse, or combinations thereof (col. 27, lines 32-54 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson within Cunningham and Denny. The motivation for doing so would have been to control abuse by refusing to process the prescription (col. 27, lines 32-54 of Edelson).

***Response to Arguments***

22. Applicant's arguments with respect to claims 1 and 22 have been considered but are moot in view of the new ground(s) of rejection.

23. Applicant's arguments filed 6/3/09 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 6/3/09.

(1) Applicant argues that numerous secondary considerations further illustrate the uniqueness and nonobviousness of the claimed invention.

(A) As per the first argument: the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

***Conclusion***

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches inventory monitoring and dispensing system for medical items (5,790,409); a computerized prescription system for gathering and presenting information relating to pharmaceuticals (US 2002/0042725 A1); and permission based marketing for use with medical prescriptions (US 2003/0050799 A1).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./  
Examiner, Art Unit 3686  
In  
7/28/09

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
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